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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,991	01/25/2002	Tjorvi Ellert Perry	701039-051580	3545
26248	7590	08/18/2004	EXAMINER	
NIXON PEABODY LLP 101 FEDERAL ST BOSTON, MA 02110			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	
DATE MAILED: 08/18/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/056,991

Applicant(s)

PERRY ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-33 is/are pending in the application.
- 4a) Of the above claim(s) 17-31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 and 33 is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☒ Claim(s) 15, 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of group I, claims 1-16, in the response dated 05 Nov. 2003 is acknowledged.
2. Claims 17-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response dated 05 Nov. 2003.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-7, 9-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al.(Clin. Phys. Physiol) in view of Tindale et al.(Clin. Phys. Physiol).

With respect to claim 1, the reference of Fischer et al. (See Figure 2 and pages 64-66) discloses an apparatus comprising: (a) a base capable of supporting a tissue-engineered construct, the base including a housing having an inlet port and an outlet port; (b) a main fluid circuit for allowing flow of a fluid media through the housing, the main fluid circuit having an efferent section in fluid communication with the outlet port and an afferent section in fluid communication with the inlet port; (c) pressure means in fluid communication with the main fluid circuit for generating physiologic flow of the fluid media through the main fluid circuit, (d) resistance means in fluid communication with the main fluid circuit for replicating an afterload characteristic, the resistance means positioned distal to a tissue-engineered construct on the efferent section of the main circuit; and (e) control means (See page 66) in electronic communication with said pressure means for adjustably controlling the pressure of the fluid media in the main fluid circuit at a level which replicates intraluminal flow, wherein said intraluminal flow of the fluid through said main fluid circuit hemodynamically conditions a tissue-engineered construct prior to in vivo implantation in a ventricular outflow tract.

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Claims 1 and 3 differ by reciting that the main fluid circuit includes an auxiliary fluid circuit with a check valve.

The reference of Tindale et al. discloses (See Figure 2) that it is known in the art to provide a valve perfusion system with an auxiliary circuit that returns fluid to a reservoir tank.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with an auxiliary circuit for the known and expected result of allowing regurgitant flow of fluid from the main fluid circuit as evidenced by Figure 2 of Tindale et al.

With respect to claims 4-7, the pressure means is a piston pump with a check valve and positioned upstream of the housing.

With respect to claim 9, the housing is hermetically sealed (See Figure 2).

With respect to claims 10 and 11, the housing is made of acrylic (See page 65).

With respect to claim 12, the controller includes a computer (See page 66).

With respect to claim 14, the resistance means is capable of replicating aortic pressure (See page 67).

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al.(Clin. Phys. Physiol) in view of Tindale et al.(Clin. Phys. Physiol) and Nguyen et al.(US 5,272,909).

The combination of the references of Fischer et al. and Tindale et al. has been discussed above.

Claim 8 differs by reciting the use of a bellows pump for pumping the perfusion fluid.

The reference of Nguyen et al. discloses that a system for the testing or perfusion of venous vales can include a bellows pump(298) (See Figure 3).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a pump in the system of the modified primary reference for the known and expected result of providing an art recognized means for perfusing a venous valve using a pump device that is capable of generating flow conditions that are the same as those *in situ* (See column 3, lines 30-34).

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al.(Clin. Phys. Physiol) in view of Tindale et al.(Clin. Phys. Physiol) and Thorne et al.(US 3,738,914).

The combination of the references of Fischer et al. and Tindale et al. has been discussed above.

Claim 13 differs by reciting that the resistance means includes a compliant tubing having elastic recoil.

The reference of Thorne et al. discloses that it is known in the art to employ an afterload device (44) that includes a tubular silicone bladder (See column 2, lines 30-46).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the afterload device of the Thorne et al. reference in the system of the primary reference for the known and expected result of providing an alternative

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means recognized in the art for creating and/or adjusting the pressure within the fluid circuit as required of the primary reference of Fischer et al.

***Allowable Subject Matter***

9. Claims 32 and 33 are allowed.

10. Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: The above claims would be allowable because the prior art of record fails to teach or fairly suggest providing a compressible container in fluid communication with the construct holding housing for allowing radial movement of the construct during flow of the media through the main fluid circuit.

***Response to Arguments***

12. Applicant's arguments filed 07 June 2004 have been fully considered but they are not persuasive.

With respect to the rejection of claims 1, 4-6, 8-10 and 14 over the reference of Nguyen et al. under 35 USC 102 (b), the amendment to claim 1 that incorporates the limitations of

cancelled claim 2 is sufficient to over come the rejection of the above claims over the reference of Nguyen et al. under 35 USC 102(b).

With respect to the rejection of claims 1, 4-7, 9-12 and 14 over the reference of Fischer et al. under USC 102 (b), the amendment to claim 1 that incorporates the limitations of cancelled claim 2 is sufficient to over come the rejection of the above claims over the reference of Fischer et al. under 35 USC 102(b).

With respect to the rejection of claims 11 and 13 over the combination of the references of Nguyen et al. in view of Thorne et al. and the rejection of claim 13 over the combination of the references of Fischer et al. in view of Throne et al., the amendment to claim 1 that incorporates the limitations of cancelled claim 2 is sufficient to over come the rejection of the claims over the combination of the references of either Nguyen et al. or Fischer et al. in view of Thorne et al. Note the limitation of claim 13 is now addressed by the combination of the references of Fischer et al., Tindale et al. and Throne et al.

With respect to the rejection of claims 2 and 3 over the combination of the references of Fischer et al. in view of Tindale et al., Applicants argue that the combination of the references is improper because the reference of Fischer et al. fails to teach the claimed auxiliary circuit and fails to provide no specific or even general motivation to combine the teachings of Tindale without prior knowledge of Applicants' invention. As a result, Applicants further argue that the Examiner has employed impermissible hindsight reconstruction.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,



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suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, while the primary reference of Fischer et al. does not specifically recite or suggest the use of an auxiliary circuit, the reference of Tindale et al. clearly discloses the use of an auxiliary circuit as recited in the instant claims. Note both the references of Fischer et al. and Tindale et al. are drawn to devices or systems for perfusing a heart valve with a perfusion medium. One of ordinary skill in the art when reviewing the disclosures of the Fischer et al. and Tindale et al. would have recognized that any of the structures disclosed in the system of Tindale et al. could be incorporated into the system of Fischer et al. for the known and expected result of providing the same function in the system of Fischer et al. as is provided in the system of Tindale et al. In this case, one of ordinary skill in the art would have been motivated to provide the auxiliary circuit disclosed by the reference of Tindale et al. in the system of Fischer et al. for the known and expected result of providing an art recognized means for bypassing the perfusion circuit and returning perfusion fluid to the system reservoir (See Figure 2 of Tindale et al.)

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As discussed above, the motivation for the modification was not

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gleaned from the instant disclosure, rather the motivation is provided solely by the disclosure of the prior art linked with the level of one having ordinary skill in the art.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Except for Applicants' comments with respect to impermissible hindsight reconstruction, Applicants' comments are draw solely to the deficiencies of the reference of Fischer et al.

For these reasons, Applicants' arguments are not found to be persuasive and the rejections of the claims have been maintained.

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB